

**PURGED** <sup>RTK</sup>

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

January 9, 1997

cc: HFI-35/FOI Staff  
BWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 97 - 22

Mildred Koepsel  
Koepsel's Farm Market  
9668 Highway 57  
Baileys Harbor, Wisconsin 54202

Dear Ms. Koepsel:

An inspection of your firm on November 21 and 26, 1996, by Investigator Gerald E. Scholze revealed serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Parts 108 and 114. By virtue of these deficiencies the products processed at your facility are adulterated within the meaning of Section 402(a)(3) and 402(a)(4) of the Food, Drug and Cosmetic Act (the Act).

Noted deviations include the following:

1. Your Corn Relish, Pepper Relish, Piccolilli, Pickled Veggies, Cherry Peppers, Zucchini Pickles and Sweet Pickle Carrots do not have a process filed with FDA [21 CFR 108.25(c)(2)].
2. Lack of sufficient control in that there are no written procedures for pH testing of raw products, brine batches and finished products [21 CFR 114.80(a)(2)].
3. Product containers are not marked with separate codes for each batch of product [21 CFR 114.80(b)].

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4. Two pH values have not been determined on each sample [21 CFR 114.90(a)(5)(iii)].
5. There is no record of examinations of raw materials and packaging materials [21 CFR 114.100(a)].

The labels do not have the nutrition labeling required by the Nutrition Labeling and Education Act of 1990 (NLEA). If you believe you are entitled to an exemption under the regulations for low-volume foods or small businesses, you must file a notice of eligibility and provide the information necessary to verify your exempt status except for food products with an annual sales of fewer than 10,000 total units. A model small business food labeling exemption notice and instructions for completion are enclosed. A copy of the regulations covering exemptions and the recent revision of August 7, 1996, are also enclosed.

Also in regard to the labels, net contents must be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semi-solid or viscous or a mixture of solid and liquid.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice such as seizure and/or injunction.

Within 15 days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days state the reason for the delay and the time within which the correction will be completed. Your response should be sent to the attention of Compliance Officer Judy E. Heisick at the address indicated on the letterhead.

Sincerely yours,



John Feldman  
Director  
Minneapolis District